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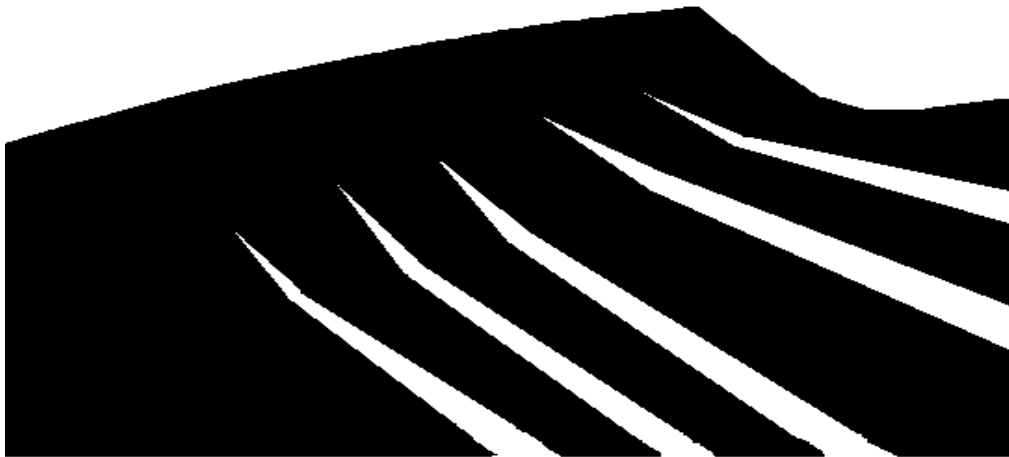
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LANL-YMP-QP-12.3, R3

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CONTROL OF MEASURING AND TEST EQUIPMENT AND STANDARDS

LOS ALAMOS QUALITY PROGRAM



APPROVAL FOR RELEASE

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Los Alamos

Yucca Mountain Site
Characterization Project

HISTORY OF REVISIONS

REVISION NO.	EFFECTIVE DATE	PAGES REVISED	REASON FOR CHANGE
R0	01/31/94	N/A	Supersedes LANL-YMP-QP-12.1.
R1	08/01/94	All	Complete rewrite to streamline process and incorporate RTN review comments.
R2	07/31/95	3, 5, 6, 9-11, & Atts. 2 & 3	Editorial revision to change Corrective Action Reports (QP-16.4) references, to Performance/Deficiency Reporting (AP-16.1Q).
R3	08/08/96	All	Complete rewrite to incorporate revised QARD requirements, to streamline the process, and delete M&TE Coordinator Activities.

CONTROL OF MEASURING AND TEST EQUIPMENT AND STANDARDS

1.0 PURPOSE

This procedure describes the process to identify, maintain, and control measuring and test equipment (M&TE) and standards for the Los Alamos National Laboratory (Los Alamos) Yucca Mountain Site Characterization Project (YMP or Project).

2.0 SCOPE

- 2.1 This procedure governs M&TE, including integral software, programmable hardware, and standards used on the Los Alamos YMP. Software developed or modified by the user shall be controlled in accordance QP-03.20.
- 2.2 This procedure applies to all Los Alamos and Los Alamos-subcontractor YMP personnel (hereafter referred to as YMP personnel) who work under the Los Alamos YMP quality assurance program.
- 2.3 This procedure does not govern rulers, tape measures, levels, and similar commercial grade measuring devices that provide adequate accuracy.
- 2.4 This procedure does not govern M&TE used in one-time-only applications or gages and meters that are used in non-critical and/or "indication only" functions. These are governed by QP-03.5.

3.0 REFERENCES

YAP-15.1Q, Control of Nonconformances
LANL-YMP-QP-03.5, Documenting Scientific Investigations
LANL-YMP-QP-03.20, Software Configuration Management
LANL-YMP-QP-04.6, Procurement
LANL-YMP-QP-17.6, Records Management

4.0 DEFINITIONS

4.1 Calibration

Calibration is the process of using calibration standards to adjust or systematically standardize the output of M&TE or other standards.

4.2 Calibration Certificate

A calibration certificate is a document provided by a supplier of calibration services that attests to the accuracy of the calibration, specifies the period of calibration validity, and indicates the traceability to the calibration standard.

4.3 Certificate of Conformance

A certificate of conformance is a document signed or otherwise authenticated by an authorized individual certifying the degree to which services or calibration standards meet specified requirements.

4.4 Custodian

The custodian is an individual who ensures that a unit of M&TE is maintained and calibrated or that a standard is documented and maintained. The custodian may be the PI or an individual designated by the PI.

4.5 Measuring and Test Equipment

Measuring and Test Equipment (M&TE) is a device or system used to calibrate, measure, gage, test, or inspect physical or chemical properties of materials for the purpose of collecting data, for establishing characteristics or values not previously known, or for verifying conformance to specified requirements.

4.6 Standard

A standard is material with known values, physical constant, or a device which is the reference for standardizing the output of M&TE or other standards.

4.6.1 Consumable Standard

A consumable standard may be used up over a period of time. Examples are chemical solutions, minerals, and rocks.

4.6.2 Nonconsumable Standard

A nonconsumable standard is not used up over a period of time and may require calibration. Examples are weight sets, thermocouples, and thermometers. Non-consumable standards are documented on the M&TE Report in accordance with the requirements for M&TE.

5.0 RESPONSIBILITIES

The following personnel are responsible for activities identified in Section 6.0 of this procedure.

- Principal Investigator (PI)
- Custodian

6.0 PROCEDURE

The use of this procedure must be controlled as follows:

- If this procedure cannot be implemented as written, Los Alamos YMP personnel should notify appropriate supervision. If it is determined that a portion of the work cannot be accomplished as described in this QP, or would result in an undesirable situation, that portion of the work will be stopped and not resumed until this procedure is modified or replaced by a new document that reflects the current work practice.
- YMP personnel may use copies of this procedure printed from the controlled document electronic file; however, YMP personnel are responsible for assuring that the correct revision of this procedure is used.
- When this procedure becomes obsolete or superseded, it must be destroyed or marked “superseded” to ensure that this document is not used to perform work .

6.1 Control of Consumable Standards

- 6.1.1 The **Custodian** documents the applicable information in accordance with QP-03.5.

6.2 Control of M&TE

The **Custodian** performs the following:

- 6.2.1 Completes lines 1-8 in Section I of the M&TE Report (Attachment 1). The identifier for M&TE including non-consumable standards must be unique, e.g. serial number or property number.
 - 6.2.1.1 Defines the method and interval of calibration for each device based on the type of equipment, stability characteristics, required accuracy, intended use, and other applicable conditions affecting measurement control.
 - 6.2.1.2 Documents on line 7 of Section I of the M&TE Report any special storage and handling requirements that are necessary to maintain accuracy of the device.
 - 6.2.1.3 For M&TE calibrated at each use, enters “At each use” on line 6 in section I. Enters an N/A with initial and date on lines 19 and 21 to document that these sections are not applicable.
- 6.2.2 Verifies that standards are traceable to nationally recognized standards or physical constants.
 - 6.2.2.1 If a standard having traceability to nationally recognized standards or a physical constant does not exist, the basis for

calibration is documented on line 9 of the M&TE Report. If a nationally recognized standard or physical constant does exist enters N/A on line 9.

6.2.3 Verifies that calibration standards have a greater accuracy than the M&TE being calibrated. If standards with an accuracy equal to the M&TE being calibrated must be used, and can be shown to be adequate for the requirements, the **Custodian** performs the following:

6.2.3.1 Documents the basis for calibration acceptance on line 10 of the M&TE Report.

6.2.3.2 Obtains authorization for the calibration acceptance by having the Principal Investigator (PI) sign and date on line 11 of the M&TE Report.

6.2.4 Enters N/A on line 10 if a reference standard greater than the calibration tolerance exist. Signs and dates the signature block on line 11 for initial entries or for subsequent changes to the information in Section I.

6.2.5 Completes the M&TE Report per subsection 6.3 or 6.4.

6.3 Calibration of M&TE at a Set Frequency

The **Custodian** performs the following:

6.3.1 If the calibration is to be performed by an agency outside Los Alamos, initiates a purchase request in accordance with QP-04.6.

OR

6.3.2 If the calibration is to be performed by the Los Alamos YMP, contacts the Los Alamos National Laboratory (LANL) Standards and Calibration Department.

6.3.3 Verifies that the calibration is performed and that the calibrator completes Section II of the M&TE Report. This information may be supplied on the M&TE Report or on separate documentation traceable to the M&TE Report.

6.3.4 Completes Section III of the M&TE Report, as applicable, and signs and dates line 21 of the M&TE Report.

6.3.5 If the M&TE accuracy was found to be out of tolerance during calibration or could not be calibrated, the **Custodian** performs the requirements stated in subsection 6.5.

6.3.6 Verifies that a label, tag, or other suitable marking is placed on or adjacent to the M&TE that lists, as a minimum, the following information:

- The Los Alamos M&TE Identifier as listed on the M&TE Report.

- The date the M&TE was calibrated.
- The next calibration due date.

6.3.7 Verifies that the M&TE Report is complete and that all lines contain the applicable information, or that the information is attached.

6.3.8 Transmits the completed M&TE Report and any attachments to a Record Processing Center (RPC) in accordance with subsection 6.7.

6.4 Calibration of M&TE that is “Calibrated at each use”

The **Custodian** performs the following:

6.4.1 Ensures that the user documents the calibration and use of M&TE calibrated “at each use” in accordance with QP-03.5.

6.4.2 Places a label, tag, or other suitable marking on or with the M&TE that lists, as a minimum, the following information:

- Los Alamos M&TE Identifier as listed on the M&TE Report.
- The instrument is calibrated at each use.

6.4.3 Transmits the completed M&TE Report to a Record Processing Center (RPC) in accordance with subsection 6.7 of this procedure.

6.5 Out-of-calibration M&TE

M&TE that are out of calibration are not to be used until recalibrated. M&TE that are calibrated at a set frequency are considered to be out-of-calibration under the following conditions:

- if the calibration due date has passed,
- if the M&TE is a sensitive instrument that has been moved,
- if results are known to be in error,
- if equipment software has been upgraded, or
- if any condition exists that could be expected to have changed the M&TE’s calibration.

6.5.1 The **Custodian** performs the following for out-of-calibration M&TE:

6.5.1.1 Controls the use of the M&TE for Los Alamos YMP activities by placing a tag, label, or other suitable marking to indicate that it is out-of-calibration.

6.5.1.2 Verifies that out-of-calibration M&TE are either calibrated according to subsection 6.3 or are removed from the Los Alamos YMP according to subsection 6.6.

- 6.5.2 If the M&TE accuracy was out of tolerance before calibration, could not be calibrated within the specified tolerance, or was lost, and was used to collect data governed by Los Alamos YMP QPs or DPs since its last calibration, ensures that the PI initiates an M&TE Evaluation Report (Attachment 2).
 - 6.5.2.1 If data were not affected by the out of tolerance condition, attaches the M&TE Evaluation Report to the M&TE Report.
 - 6.5.2.2 If data were affected, initiates a Nonconformance Report according to YAP-15.1Q to document the evaluation and disposition of the validity of results, and attaches the M&TE Evaluation Report to the M&TE Report.
 - 6.5.2.3 Transmits the M&TE report to a RPC in accordance with subsection 6.7 of this procedure.
- 6.5.3 The **custodian** verifies that M&TE that are consistently out of calibration, are either repaired or replaced. If the M&TE has been lost, verifies that it has been removed from the system.

6.6 Removing M&TE from a Los Alamos YMP Control System

The **Custodian** performs the following:

- 6.6.1 Ensures that the M&TE is calibrated according to subsection 6.3 prior to removal, if used to collect Los Alamos YMP data since the last calibration.
- 6.6.2 Indicates in Section III of the M&TE Report that the M&TE was removed from service on a given date and completes line 21.
- 6.6.3 Transmits the M&TE Report to a RPC in accordance with subsection 6.7 of this procedure.

6.7 Submittal of Record Package to the Records Package Center (RPC)

The **Custodian** performs the following:

- 6.7.1 Prepares a record package for each M&TE that includes copies of applicable M&TE Reports, M&TE Evaluation Reports, attachments, and memoranda.
- 6.7.2 Verifies that the record package lists the M&TE as the traceability designator or record identifier in accordance with QP-17.6.

7.0 RECORDS

The following records result from this procedure:

- M&TE Report
- M&TE Evaluation Report
- Related correspondence

NOTE: Calibration documentation contained in notebooks for M&TE calibrated at each use are submitted to the Records Processing Center (RPC) in accordance with QP-03.5.

8.0 TRAINING REQUIREMENTS

- 8.1 All custodians and YMP personnel; who either conduct calibrations or maintain M&TE or reference standards are required to train to this procedure.
- 8.2 Training to this procedure is accomplished by “read only.” Personnel who initiate a Nonconformance Report will also need “read only” training to YAP-15.1Q.

9.0 ATTACHMENTS

Attachment 1: M&TE Report (1 page)
Attachment 2: M&TE Evaluation Report (1 page)

M&TE REPORT

SECTION I. (Custodian completes)

1. M&TE Identifier: _____ 2. Description: _____ 3. Location: _____
4. Capacity/Range: _____ 5. Tolerance Required: _____ 6. Calibration Frequency: _____
7. Special Handling, Storage, and Maintenance Instructions:
8. Assigned Custodian: _____
Print name
9. A nationally recognized reference standard does not exist, and the basis for calibration is as follows:
10. The accuracy of the reference standard equals the required calibration tolerance, and the basis for the calibration acceptance is as follows:

NOTE: Custodian signature only required when entering M&TE into Los Alamos YMP control/system or for subsequent changes to the information in Section I.

11. Custodian _____
Print name Signature Date

SECTION II. (Calibrator completes, or information provided on separate documentation)

12. Calibration Procedure/Revision No.: _____ 13. Reference Standard Identifier: _____
14. Reference Standard Description: _____ 15. Reference Standard Accuracy: _____
16. Accuracy before calibration: _____ 17. Accuracy after calibration: _____
18. ☐ M&TE was within tolerance before calibration ☐ M&TE has been calibrated within the specified tolerance.
- ☐ M&TE was not within tolerance before calibration ☐ M&TE could not be calibrated within the specified tolerance.

19. Calibrator: _____
Print name Signature Date

SECTION III (Custodian completes)

20. Calibration Status
- ☐ M&TE calibration checked and within tolerance. ☐ M&TE removed from Los Alamos YMP this date: _____
- ☐ M&TE not used since last calibration ☐ M&TE not within tolerance before calibration-not used since last valid calibration.
- ☐ M&TE not within tolerance required before calibration - M&TE evaluation RPT attached ☐ M&TE's next calibration due date: _____

21. Custodian: _____
Print name Date

M&TE EVALUATION REPORT

SECTION I. (PI Completes the following)

M&TE or Standard Identifier _____

Description _____

On _____ the M&TE or Standard identified above:
(Date)

- ☐ Was found to be out of tolerance
- ☐ Could not be calibrated
- ☐ Was determined to be lost

Was the device used to collect data?

- ☐ NO, complete Section III
- ☐ YES, determine if data collected were affected by the identified condition and document the results in Section II.

SECTION II. (PI Completes the following)

Evaluation:

- a) Identify data collected:
- b) Process monitored:
- c) Notebooks reviewed:
- d) Conclusion: The validity of results obtained with the M&TE or Standard and the acceptability of data collected since the last calibration have been evaluated as required, and is documented as follows:

- ☐ Data are acceptable Complete Section III
- ☐ Data are unacceptable Initiate NCR and complete Section III NCR NO. _____

SECTION III. (PI completes the following)

The impact of the identified condition has been evaluated.

(SIGNATURE)

(DATE)